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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,247	04/13/2007	Ge Ming Lui	266622	6960

23548 7590 02/17/2010

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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
02/17/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/575,247	LUI, GE MING	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *5-8,10-18 and 23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,19-22 and 26-39* is/are rejected.

7)☒ Claim(s) *1,26,29,31 and 36-38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20061211*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-4, 9, 19-22 and 26-39 in the reply filed on 10/5/2009 is acknowledged. Claims 5-8, 10-18 and 23-25 are hereby withdrawn from consideration, pursuant to 37 CFR 1.42(b), as being directed to non-elected inventions.

Priority

Acknowledgement is made of the instant application being a national stage entry under 35 USC 371 of international application PCT/US04/033194, filed 10/8/2004. Acknowledgement is further made of Applicants' claim for priority under 35 USC 119(e) to US provisional applications 60/510,358 and 60/510,348, both filed 10/10/2003.

Formal Matters

It has been noted that there are two claims numbered 28; such is inappropriate, as a claim number may only be used once in an application. In order to provide compact prosecution these claims have been treated on the merits and the claims have been referenced as claim 28(i) and 28(ii) (in sequential order). To correct this deficiency it is recommended that Applicants cancel ALL pending claims (1-39) and submit any claims on which Applicants wish to continue prosecution as NEW claims 40-….. The claim numbers CANNOT be adjusted within the current listing (i.e. the second claim 28 and subsequent claims 29-39 CANNOT be amended to be claims 29-40). Correction is required.

Claim Objections

Claims 1, 26, 29, 31 and 36-38 are objected to because of the following informalities:

In claims 1 and 38, it appears the first lines of the claims should read, "...the growth and attachment..." Appropriate correction is required.

In claim 26, the abbreviation "BCE-ECM" is not a common term in the art, thus the full term "bovine corneal epithelial cell-extracellular matrix" should be written out, followed by the abbreviation in parentheses, the first time the term is used, *e.g.* "...with bovine corneal endothelial cell-extracellular matrix (BCE-ECM)…" Appropriate correction is required.

Claims 29 and 31 must start with an article of speech, i.e. "A laboratory apparatus..." Correction is required.

Claims 36 and 37 are independent claims and therefore should begin with the article "A," not "The," as they are not further defining the article produced by claims 34 or 35, but rather claiming the actual article(s).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 9, 19-22, 27-35, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, which is directed to an improved surface of the growth an [*sic*: and] attachment of cells comprising a biopolymer coated with a high quality, hydrogen-free, diamond-like carbon surface, is considered indefinite for the following reason:

First, a biopolymer is not coated with a *surface* (i.e. diamond-like carbon *surface*), but rather with a material or coating.

Second, the term "high quality" in the second line of the claim, is a relative term which renders the claim indefinite. The term "high quality" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, it is unclear how quality is measured, i.e. what physical properties affect quality? Without knowing how quality is determined, requiring the claimed surface to have 'a high quality' renders the claim indefinite.

Claims 2-4 and 9 inherit the deficiencies of claim 1, and therefore are rejected on the same basis.

Claims 9, 21 and 27 are held as indefinite because of the recitation of the term "RGDS," while it would appear to refer to the peptide Arg-Gly-Asp-Ser, no explicit definition is provided in the disclosure, and thus it cannot properly be concluded to what this term is intended to refer. The metes and bounds of the claim can therefore not be determined. Peptide sequences of greater than four amino acids must be identified by a proper SEQ ID NO, provided in accordance with 37 CFR 1.821. Furthermore, the use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules.

In claim 19 it appears the word "cell" has been omitted from the third line of the claim, i.e. "…capable of supporting neuronal cell growth coated with Diamond-Like Carbon.." The omission renders the claim indefinite. "Neural cell growth" would also be appropriate, and would better correlate with the preamble. Claims 20-22 inherit this deficiency, and therefore are rejected on the same basis.

Claims 20 and 27 require the growth medium to further comprise "May Polymer." It is not known what "May Polymer" is, as it is not clearly defined in the specification, nor an art recognized term. If "May Polymer" is the name of a brand name or trademarked product the generic terminology must be

used in the claims, and disclosed in the specification. Claims 21, 22, 28(i) and 28(ii) inherit this deficiency, and therefore are rejected on the same basis.

Claims 21 and 28(i) further limit the "May Polymer" by requiring an attachment reagent to be embedded or incorporated therewithin, however the claim is held indefinite because the Markush-type language does not clearly define the alternative reagents. Specifically, the claim recites "the attachment reagent [comprises] one or more of the following: laminin, fibronectin, RGDS, bFGF conjugated with polycarbophil, EGF conjugated with polycarbophil, and heparin sulfate *or Nerve Growth Factor*" It is the final species of Nerve Growth Factor that renders the claim confusing- is NGF intended to be included in the group of species from which one or more of species of attachment reagent may be selected? Or is NGF a separate genus of molecules which may be selected *instead of* the one or more attachment reagents listed? Clarification is required. Claims 22 and 28(ii) inherit this deficiency and therefore are rejected on the same basis.

Furthermore, in claims 21 and 28(i) there is insufficient antecedent basis for the limitation "said unit" at line 7 of the claim. Claims 22 and 28(ii) inherit this deficiency, and therefore is rejected on the same basis.

Claim 29 is considered indefinite because it is directed to a laboratory apparatus *comprising said apparatus*. This circular references is inappropriate. Furthermore, reference to cells and cellular media is unclear- does the claimed laboratory apparatus comprise cells and cellular media? If not, then such is an intended use and is of no significance to claim interpretation. It appears the claim should read, "A laboratory apparatus having an inside and an outside surface, the inside surface being coated with a film of diamond-like coating." Claim 30 inherits this deficiency, and thus is rejected on the same basis.

Claim 30 is rejected because the recited species of "slides" does not appear to correlate with parent claim 29, because slides do not have an inside and outside surface, wherein the inside surface may be coated with a diamond-like coating.

Claim 31 is ambiguous, and thus indefinite, because it is directed to both an apparatus and a method for the manufacture of the apparatus; therefore it is not clear what applicant is intended to claim the apparatus, per se, or the method of making such. See *Ex parte Lyell,* 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) & MPEP 2173.05(p). While the claim is indefinite, in order to provide compact prosecution, the claims will be examined as apparatus (product) claims in a product-by-process manner, wherein the method of producing the apparatus will be considered so far as it effects the apparatus itself. Claims 32 and 33 inherit this deficiency and thus are rejected on the same basis.

Claim 34 is held as indefinite because the claim fails to articulate *of what* the inside surface is applied to. It appears the claim should read, "...to an inside surface of the laboratory apparatus a film of...." However, it must then be clarified that the laboratory apparatus actually *has* an inside surface in order to provide proper antecedent basis.

Claim 35 is rejected for lacking antecedent basis for the limitation "the inside surface of said apparatus", as it is not defined that the apparatus necessarily has an inside surface (an inside surface is not an inherent physical property of any and all laboratory apparatuses).

Claim 38, which is directed to an improved surface of the growth an [*sic*: and] attachment of cells comprising a synthetic biopolymer coated with a high quality, hydrogen-free, diamond-like carbon surface, is considered indefinite for the following reason:

First, a biopolymer is not coated with a *surface* (i.e. diamond-like carbon *surface*), but rather with a material or coating.

Second, the term "high quality" in the second line of the claim, is a relative term which renders the claim indefinite. The term "high quality" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, it is unclear how quality is measured, i.e. what physical properties affect quality? Without knowing how quality is determined, requiring the claimed surface to have 'a high quality' renders the claim indefinite. Claim 39 inherits the deficiencies of claim 38, and therefore is rejected on the same basis.

Claim 39 is further rejected because the species recited therein are not clearly defined or delineated. The claim recites "an acrylic polymer *and its derivatives or copolymers*" (and then recites what appear to be illustrative examples of such copolymers) or "a polyvinyl alcohol *and its derivatives and copolymers.*" Is "an acrylic polymer *and* its derivatives" a single species? Are copolymers of acrylic polymer a separate species? Are polymethyl methacrylate, poly-N-isopropylacrylamide or poly-2-hydroxymethacrylate included within the scope of the claim? Or are they merely prophetic examples? Are "polyvinyl alcohol *and* its derivates *and* copolymers" a single species? Correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 31-33 are rejected under 35 U.S.C. 101 because the subject matter claimed by independent claim 31 does not fall into a single statutory class of invention.

Claim 31 claims both an apparatus and a method of manufacturing the apparatus; therefore it is directed to neither an apparatus nor the method of making such, but rather encompasses or overlaps two different statutory classes of invention. The language of 35 USC 101 prohibits overlap between two different statutory classes in a single claim as it is drafted so as to set forth the statutory classes of invention in the alternative only. See *Ex parte Lyell,* 17 USPQ2d 1551 (Bd. Pat. App. & Inter. 1990).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 39 defines the synthetic polymer of claim 38 as an acrylic polymer *and its derivatives or copolymers*, or a polyvinyl alcohol *and its derivatives and copolymers*.

To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics; and (2) a representative number of species within the genus must be disclosed. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

In giving the term 'derivatives [of acrylic polymers and polyvinyl alcohols]' their broadest reasonable interpretations, the number and types of compounds which can be considered *derivatives* of

either of acrylic polymers or polyvinyl alcohol, is extraordinarily great, and can be interpreted to even include elemental carbon and hydrogen as derivatives. In giving the term 'copolymers [of acrylic polymers and polyvinyl alcohols]' their broadest reasonable interpretation, the number and types of polymeric compositions which is encompassed is virtually unlimited. However, in contrast to the great breadth of the instant claim, Applicants have only disclosed the species of polymethyl methacrylate, poly-N-isopropylacrylamide and poly-2-hydroxymethacrylate (no species of polyvinyl alcohol copolymers are disclosed).

Regarding disclosure of identifying characteristics of the claimed molecules a review of the specification fails to provide a definition of what structural characteristics of acrylic polymers and/or polyvinyl alcohols the derivatives and copolymers encompassed by the current claims must have; Applicants have not identified any particular core chemical structure or function (along with a correlation between function and a specific conserved structure) of acrylic polymers and polyvinyl alcohols which must be shared by all derivatives and copolymers thereof; and thus one of ordinary skill in the art would not immediately envisage all derivatives of acrylic polymers and polyvinyl alcohols, as currently claimed. Therefore Applicants have not disclosed the identifying characteristics of the claimed molecules.

Regarding disclosure of a representative number of species within the genus a review of the specification shows that Applicants have disclosed acrylic polymers and polyvinyl alcohols, per se, and polymethyl methacrylate, poly-N-isopropylacrylamide and poly-2-hydroxymethacrylate as examples of derivatives of acrylic polymers. Disclosure of a limited subset of species does not constitute a representative number for such a broad genus as is encompassed by the breadth of 'derivatives of acrylic polymers and polyvinyl alcohols.' Therefore Applicants have not disclosed a representative number of species, as would be required to support description and to show possession of the entire genus.

Thus, one of ordinary skill in the art, in looking to the instant specification, would not be able to determine that Applicants were in possession of the invention, as claimed, at the time the invention was

made. Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 30, 34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lu et al (Bio-Medical Materials and Engineering, 1993).

Lu et al disclose depositing diamond-like carbon films onto the surface of plastic tissue culture dishes to produce tissue culture dishes having a coating of diamond-like carbon film present thereupon. Tissue culture dishes necessarily have an inside and outside surface, wherein the inside surface is in contact with the cells; the coating was applied to the inner surface which was to be in contact with the cells (See Lu et al, Pg. 224, "Diamond-like Carbon Film Deposition"). Human hematopoietic myoblastic ML-1 cells were cultured on the diamond-like carbon-coated dishes and were reported to successfully grow thereupon (See Lu et al, Pg. 224-5, "Results"); therefore the DLC-coated dishes are suitable for supporting attachment and growth of cells.

The tissue culture dishes are considered to read on a laboratory apparatus. Therefore, Lu et al is held to anticipate both the method of depositing the diamond-like carbon film on tissue culture dish (laboratory apparatus) (claim 34) and the diamond-like carbon coated tissue culture dish (laboratory apparatus) thereby produced (claims 29, 30 and 36).

Claims 31-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ignatius et al (Journal of Biomedical Material Research, 1998).

Ignatius et al disclose depositing either metal or hydrogen-free, diamond-like carbon (dlc) coatings onto glass coverslips; coated and uncoated coverslips were then incubated with poly-d-lysine (PdL); some of the PdL-treated coverslips were further coated with one of laminin, fibronectin, or collagen IV coatings (See Ignatius et al, Pg. 265-266, "Materials and Methods: Substrate Preparation"). The coverslips coated with dlc and laminin are relied upon in the instant invention.

Neurons from the CNS of chick embryos were cultured on the different coverslips; the neural cells were reported to attach and extend neurite outgrowths (grow) on the dlc and laminin-coated coverslips (See Pg. 269, first and second paragraphs "Assays"- first paragraph "Discussions" & Fig. 4 on Pg. 270); Therefore the dlc- and laminin-coated coverslips are suitable for supporting attachment and growth of cells.

The glass coverslips are considered to read on laboratory apparatus; the diamond-like carbon coating is hydrogen-free (See Pg. 266, "Results: Substrates"); the laminin coating is considered to read on at least one other extracellular matrix coating which the diamond-like coating is layered upon. It is further noted that because laminin is found within the ECM deposited by bovine corneal endothelial cells, the laminin coating is considered one and the same as BCE-ECM, the source (BCE) being considered a product-by-process limitation. Therefore Ignatius et al is held to anticipate both the method of depositing the diamond-like carbon film and laminin (an ECM coating layer) on a laboratory apparatus (claims 34 and 35) and the laboratory apparatus coated with laminin (an ECM coating layer) and diamond-like carbon coating thereby produced (claims 31-33, 36 and 37).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 9, 19, 26, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignatius et al (Journal of Biomedical Material Research, 1998), in view of Lu et al (Bio-Medical Materials and Engineering, 1993).

The teachings of Ignatius et al are set forth above. Briefly, Ignatius et al is cited for their disclosure of a method of depositing hydrogen-free, diamond-like carbon coating onto glass coverslips, and then further coating the same coverslips with an additional layer of ECM material, such as laminin; the double-coated substrates were then used to support attachment and growth of neural cells. In disclosing the method, Ignatius et al necessarily disclose the coated coverslips, per se.

Ignatius et al differ from the improved surface of claims 1-4, 9, 19, 26, 38 and 39 in that Ignatius et al use glass coverslips, not biopolymer substrates.

However, given that the level of skill of the artisan in the field of cell biology is extremely high, being that of accomplished scientists having experience with cell culture technique, usually holding advanced degrees, it is submitted that the differences between the teachings of Ignatius et al and the current invention would have been found *prima facie* obvious to the artisan of ordinary skill at the time the invention was made based on the knowledge generally available to said artisans and the teachings of the prior art.

Specifically, substitution of an alternative substrate materials, such as known synthetic plastics and/or semi-solid agars, for the glass coverslips would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made. Lu et al is relied upon to evidence that cells

are routinely grown on plastic tissue culture ware, such as polyethylene, polyurethane and polycarbonates; Lu et al further evidence that diamond-like carbon coatings can successfully be deposited on such plastic culture ware (See Lu et al, "Introduction"). Such culture ware was readily available in a variety of configurations, sizes and forms, including tissue culture flasks (which may be considered to be in sheet form) and microparticles. Therefore, because both Ignatius et al and Lu et al disclose depositing diamond-like carbon coatings on substrates for subsequent use in *in vitro* cell culture, it would have been obvious to one having ordinary skill in the art to substitute one substrate material (the synthetic biopolymers taught by Lu et al) for another (the glass coverslips taught by Ignatius et al). One would have had a reasonable expectation of successfully using synthetic biopolymer substrates because Lu et al state that plastic materials are capable of receiving dlc-coatings. It has been held that substitution of one element for another known in the field is considered to be obvious, absent a showing that the result of the substitution yields more than predictable results. See *KSR International Co. v Teleflex Inc* 82 USPQ2d 1385 (US 2007) at page 1395. Therefore the improved surfaces of claims 1-4, 9, 38 and 39 is unpatentable over the teachings of Ignatius et al in view of Lu et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651